

**Remarks**

The Office Action dated October 18, 2006 has been carefully reviewed and the following comments are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

**Summary of Office Action**

1. The rejection of claims 14 to 34 under 35 U.S.C. 101 and 112, first paragraph was maintained.
2. The rejection of claims 14, 17 and 26 to 34 under 35 U.S.C. 112, second paragraph was withdrawn.
3. The rejection of claims 14, 17 and 26 to 34 under 35 U.S.C. 102(e) as allegedly being anticipated by Smith *et al.* (U.S. Patent 5,972,624) was withdrawn.

**Rejection under 35 U.S.C. 101**

The Examiner has rejected claims 14 to 34 because the claimed invention is allegedly not supported either by a specific and substantial asserted utility or by a well established utility under 35 U.S.C. 101. The Examiner has also rejected claims 14 to 34 under 35 U.S.C. 112, first paragraph, because the specification allegedly does not adequately disclose to the skilled person how to use the claimed invention.

Applicants provide herewith a declaration by the inventor, Brian O'Dowd which sets forth the utility of the claimed invention. Specifically, the claimed invention finds utility in the treatment of sexual disorders (*i.e.*, hypogonadotrophic hypogonadism) in humans. As set forth in the attached declaration, individuals who suffer from hypogonadotrophic hypogonadism do not express a functional GPR54 receptor. The nucleic acids of the invention therefore derive therapeutic utility in that they can be used in gene therapy to express active GPR54 receptor in a subject suffering from a sexual disorder (*e.g.*, hypogonadotrophic hypogonadism).

Applicants bring to the attention of the Examiner that the specification discloses that gene therapy using the claimed nucleic acids will be particularly useful in the treatment of diseases where it is beneficial to elevate GPR54 activity (see page 28, lines 9 to 19). Applicants further identify treatment of diseases that involve inappropriate expression of GPR54 including sexual

disorders (*i.e.*, hypogonadotrophic hypogonadism) as a utility of the claimed invention (see page 24, lines 17 to 25).

Applicants also bring to the attention of the Examiner that in each of the publications cited in the attached declaration, the normal sequence of GPR54 was essential in discovering the mutant forms of GPR54 associated with hypogonadotrophic hypogonadism. Specifically, oligonucleotides based on the GPR54 gene sequence were used to isolate the mutant forms of the gene and by comparing the nucleotide sequences of the genes isolated from the patients with hypogonadotrophic hypogonadism with the normal GPR54 gene sequence, the mutations responsible for this disease were identified. The specification discloses that oligonucleotides can be used to isolate DNA encoding the GPR54 receptor (see page 28, lines 20 to 32). Applicants therefore submit that these oligonucleotides can be used in the diagnosis of sexual disorders such as hypogonadotrophic hypogonadism.

Applicants specification also discloses that the GPR54 gene is located on chromosome 19p13.3 and that this information can be used in linkage analysis studies to correlated the location of disease causing genes to the location of the GPR54 gene (see page 26, line 18 to page 27, line 10). The attached peer-reviewed journal publication by de Roux *et al.* (2003) demonstrates that this information was utilized to identify the locus for hypogonadotrophic hypogonadism on chromosome 19 (19p13). Subsequent sequencing experiments determined that the GPR54 gene (found in this region) contains defects in siblings of a family suffering from hypogonadotrophic hypogonadism. Applicants therefore submit that the claimed invention finds utility in the identification and diagnosis of sexual disorders such as hypogonadotrophic hypogonadism. In view of the above arguments, Applicants submit that the rejections under 35 U.S.C. 101 and 112, first paragraph are moot and withdrawal is requested.

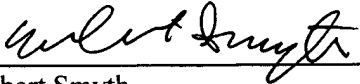
Applicants request reconsideration of the subject application in view of the above remarks and withdrawal of the rejections. It is respectfully submitted that this application is now in condition for allowance. Should the Examiner believe it to be useful, an interview with the Examiner is respectfully requested in order to discuss the foregoing claims.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37

C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: **March 20, 2006**  
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Respectfully submitted  
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